

Common Data Elements: Implementation & Impact

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Purposes of CDEs?

- Facilitate assessment of comparability across studies
- Facilitate generalization of research findings to other samples
- Facilitate parallel data analyses across different data sets
- Facilitate meta-analyses of combined data sets

Comparability...

- Are differences in findings across similar studies due to case mix differences?
 - Need “case mix” (patient specific factors) CDEs
- Are differences in findings across similar studies due to the use of different outcome measures?
 - Need “outcomes” CDEs

OR (in treatment studies)

- Do differences in findings suggest meaningful differences in treatment impact?

Generalization...

- Are prognostic or treatment efficacy findings relevant to another sample?
 - Need “case mix” CDEs

Parallel analyses...

- Is prognostic model derived from different samples consistent, when similarly adjusted?
 - Need “case mix” CDEs and “outcomes” CDEs
- Are treatment findings from different samples similar or different when similarly adjusted?
 - Need “case mix” CDEs and “outcomes” CDEs
 - What about “treatment” CDEs? – treatments must be sufficiently documented for classification, but few treatments are likely to stay static over time; that’s the point!

Meta-analyses...

- Are trends in smaller prognostic studies robust when combined for analysis? Are trends in subgroup differences in prognosis from smaller studies robust when combined for analysis?
 - Need “case mix” CDEs and “outcomes” CDEs
- Are trends in treatment differences from smaller studies robust when combined for analysis?
 - Need “case mix” CDEs and “outcomes” CDEs
 - What about “treatment” CDEs? – treatments must be sufficiently documented for classification, but few treatments are likely to stay static over time

Implications

- Developing a common database benefits from a clear set of purposes (consider the TBIMS history)
- CDEs of most obvious common utility include:
 - Case mix (patient-specific) factors
 - Outcomes
- Treatment CDEs are a more complex matter...

Implications: case mix

- Most relevant case mix factors differ depending on the outcomes of interest
 - E.g., acute mortality vs. employment
- “Scale” of case mix factors (micro/macro) depends on the intent of the study
- Case mix factors most relevant to acute studies differ from those most relevant to post-acute studies
- Outcome measures from acute studies may become case mix factors for post-acute studies
- Imaging measures and biomarkers are subcategories of case mix factors (except when under development)

Implications: outcomes

- Most relevant outcomes differ between acute studies and post-acute studies, e.g.:
 - Acute: macro functional outcomes
 - Post-acute: more specific behavioral and functional outcomes
- “Scale” of outcome measures (micro/macro) depends on the intent of the study
- (Outcome measures from acute studies may become case mix factors for post-acute studies)

A word about imaging/ biomarkers

- To function as “case mix” CDEs, these need to be in the form of specific quantified measures that have been shown to predict outcomes of interest
- Development of predictive biomarkers requires innovation in data acquisition and, more importantly, data analysis
- An interim step: standard acquisition and storage (even this should evolve, but on a slower time scale)
- Value in overtly distinguishing “validated CDEs” from “standardized storage of raw data”?

Final thoughts

- One set of CDEs? Two sets (acute/post-acute)? More?
- Balance between invitation and coercion
 - All investigators must collect the following:...
 - All investigators measuring domain X must use the following measures:...
 - Investigators measuring domain X may wish to use the following measures:...

Final thoughts (cont.)...

- Benefits of conceptualizing CDEs as case mix (patient specific factors), outcomes, [treatments]
 - Provides a yardstick for adding/revising case mix CDEs (Does variable X predict an important and commonly studied outcome better than previously?)
 - Provides a yardstick for adding/revising outcome CDEs (Is outcome domain X of clinical/economic/personal importance? Or a better measure of a domain than a current CDE?)